



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/657,363

09/08/2003

James F. Young

10271-159-999

3135

20583

7590

07/06/2009

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

07/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/657,363	Applicant(s) YOUNG ET AL.	
	Examiner MYRON G. HILL	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 86-111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 86-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>see action</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/31/09 has been entered.

Claims 86-111 are under consideration.

Priority

Applicant's petition for priority has been dismissed (mailed 6/17/09).

Accordingly, at the present time, no priority to earlier filed applications is given.

Information Disclosure Statement

Signed and initialed copies of the IDS papers filed 3/31/09, 4/20/09, 4/22/09, and 4/24/09 are enclosed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 86-111 are rejected under 35 U.S.C. 102(a) as being anticipated by Young et al. (PG Pub US 20020164326 A1, from IDS).

Young et al. teach the same invention (same disclosure).

Thus, Young et al. anticipate the claimed invention.

Claims 86-111 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al. (WO 01/55217, from IDS item E15).

Young et al. teach the same invention (same disclosure).

Thus, Young et al. anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1648

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 86, 87, 89, 91, 93, 94, 96, 98, 99, 100-103, and 105-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson *et al.* in view of Shreder.

The claims are drawn to a method of treating or preventing RSV disease using an antibody that binds the same epitope as an antibody comprising SEQ ID# 1 or 2. Each claim only requires one full VH or VL chain (the amino acid sequence) and at least some of the other VH or VL chain (an amino acid sequence).

Johnson *et al.* teach MEDI-493 and microneutralization assays (abstract, Figures 1, 2, and 5 and page 1218, column 1, last full paragraph and paragraph spanning column 1-2) and MEDI 493 comprises SEQ ID#s 1 and 2.

Johnson *et al.* do not teach an antibody with the affinity of 10E11/M.

Shreder teach that antibodies to immune responses can have affinities in the range of 10E5 /M to 10E12 /M (page 372, column 2, last paragraph).

One of ordinary skill in the art at the time of invention would have been known the different forms antibodies can be made and used.

The comparison taught by Johnson *et al.* was that MEDI-493 was more potent than the other antibody and had a lower effective dose. One of ordinary skill in the art would be motivated to use more potent anti-RSV antibodies because of their enhanced activity and lower dosing requirements. Antibodies with affinity constants of 10E11/M are known in the art.

One of ordinary skill in the art at the time of invention would have been motivated to use the antibody of Johnson *et al.* as starting material for improving or optimizing an

Art Unit: 1648

antibody knowing that MEDI-493 is an RSV-F neutralizing antibody that is useful. At the time of invention it was routine to optimize or improve antibodies to increase their binding properties.

Thus, it would have been *prima facie* obvious at the time of invention to modify the antibody used in the method of Johnson *et al.* with the expectation of success.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M-Th and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

Myron G. Hill
Patent Examiner